



Perspectives of policy makers
about RSV vaccines
and implementation issues

Rose Jalang'o
Ministry Of Health-Kenya

Disclosure statement

No conflict of interest to declare

Country brief , Kenya

Administrative : 47 Counties

Area - 582, 646 square kilometres

Population: 48 Million

Immunization target population (<1yr): 1.7 Million, **Pregnant Women :** 1.8 Million

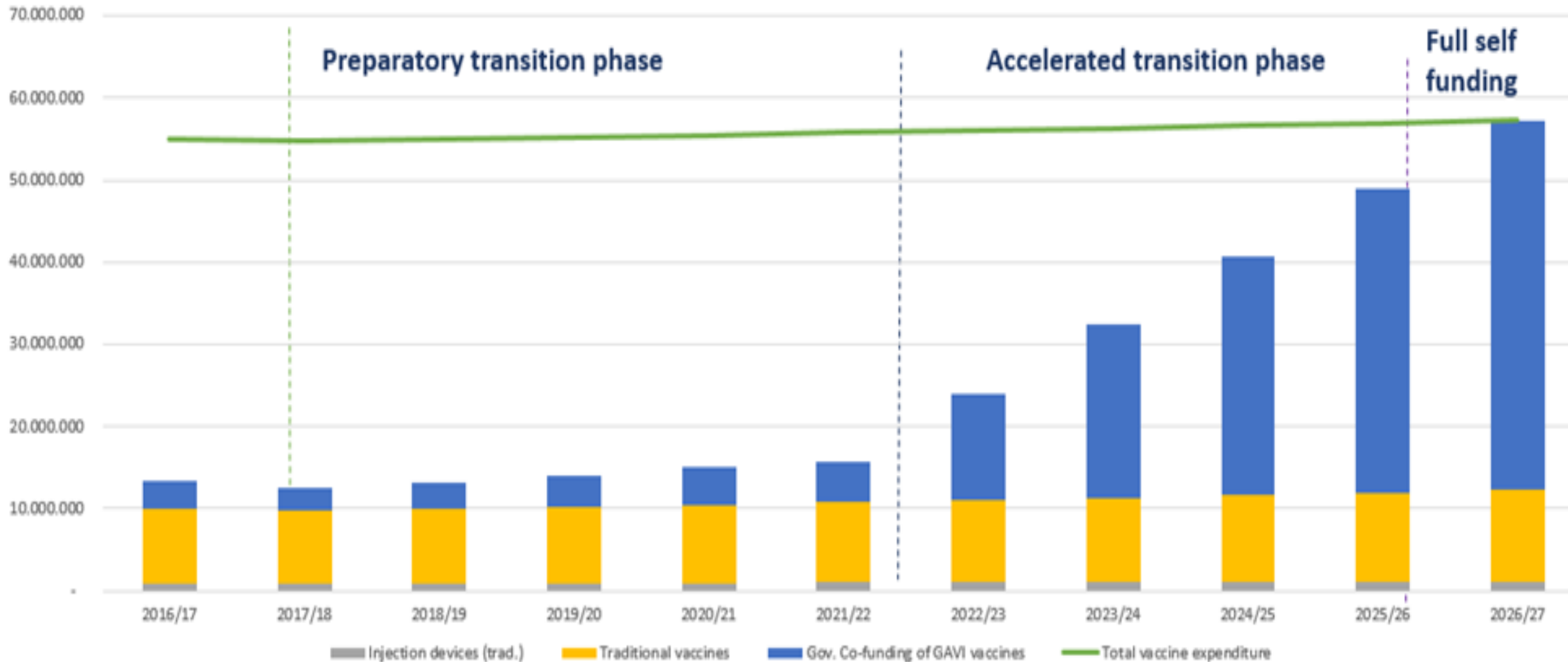
EPI services provided in 7,500 of 10,000 health facilities – Public, Private, Faith based, NGOs

Gavi Eligible Country



Vaccine	Ages of administration	Entire country	Parts of the country
BCG	At birth	✓	
OPV	At birth, 6wks, 10wks, 14wks	✓	
DPT-HepB-Hib	6wks, 10wks, 14wks	✓	
PCV10	6wks, 10wks, 14wks	✓	
Rota	6wks, 10wks	✓	
IPV	14wks	✓	
Measles Rubella 1	9 months	✓	
Yellow Fever	<i>9 months</i>		<ul style="list-style-type: none"> • Elgeyo Marakwet • Baringo • Turkana
Measles Rubella 2	18 Months	✓	
Malaria Vaccine (RTSS)	6 months,7 months,9 months ,24 months		•8 Counties with high prevalence of Malaria parasites
HPV Vaccine	10 year old girls	✓	
Td	Pregnant Mothers, Trauma patients	✓	

Immunization Funding



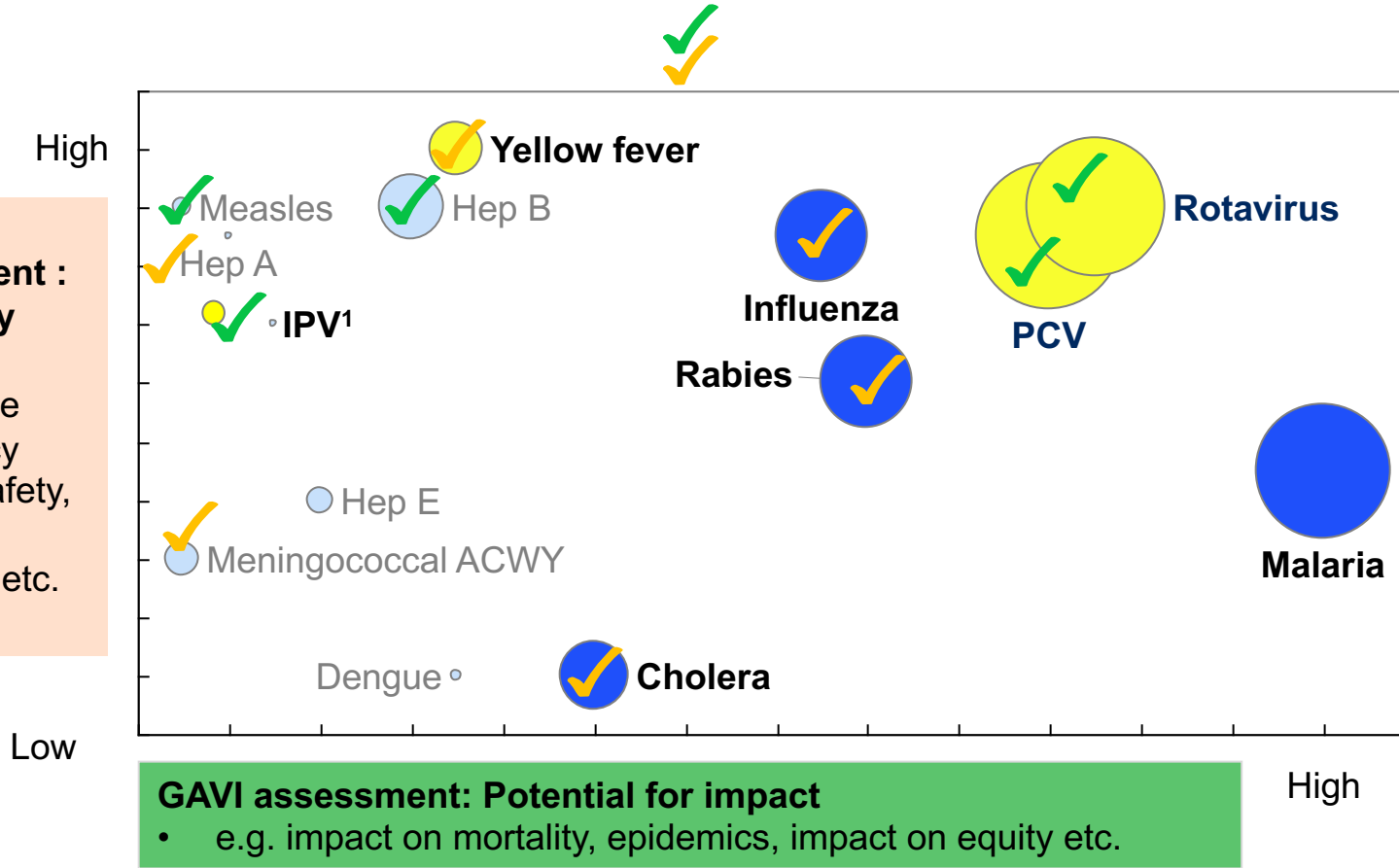
Example NVI framework: GAVI carried out its own NVI strategy to decide which vaccines to introduce, assessing feasibility vs. impact of different options

Bubble size proportional to deaths averted globally in 2015 - 2030

- Vaccines approved for GAVI funding
- Vaccines considered by GAVI but not retained
- Other new vaccines not prioritized by GAVI

GAVI assessment : Feasibility

- e.g. vaccine efficacy and safety, global costs, etc.



The Gavi framework for NVI focuses on

1. Global impact of disease
2. Cost of vaccine
3. Cost of delivery strategy
4. Ability to sustainably transition to Governments

The NVIP utilizes a similar framework while using detailed country analysis, data, and current system ability to deliver service in a sustainable manner

NVIP criteria framework on new vaccine introduction

Potential for impact

Feasibility

1

Health impact



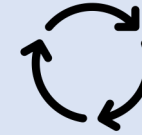
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Additional impact considerations



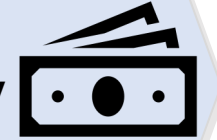
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Implementation feasibility



4

Financial viability



- Impact on child mortality / morbidity
- Impact on overall mortality / morbidity

- Epidemic potential
- Global or regional public health priority
- Herd immunity
- Socio-economic & gender inequity
- Community perspective on new vaccine introduction/disease
- Availability of alternative interventions

- Capacity and supplier base
- Vaccine efficacy and impact
- Vaccine safety profile
- Ease of integration within national cold chain systems
- Ease of integration within routine immunization schedule

- Cost in relation to other health priorities
- Vaccine procurement cost
 - With GAVI support and beyond
 - Overall and per event averted
- Other vaccine-related cost, e.g. training/data tools/ cold chain upgrade etc.

Strategy and Planning documents and processes

- cMYP
 - 5 year immunization plan aligned to the Kenya Health sector and Investment strategic plan (KHSSP)
 - Reviewed and updated annually
- Annual vaccine forecasts and AOP
 - Accuracy
 - Timely submission to UNICEF and MOH
- Procurement planning
 - Annual, Informed by AOPs, forecasts and shipment plans
 - Includes all other components necessary for running the program (O&M)
 - Submitted to MOH HQ at the beginning of calendar year

Country Decision making – Additional criteria

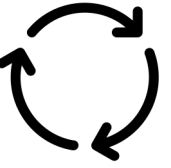


- a. Leadership by Government of Kenya
 - MOH stewardship
- b. The Role of NITAG and other advisory groups
 - KENITAG: An independent advisory group in Kenya to support the EPI program
- c. Inter Agencies Coordinating Committees? ICC support the program with leadership and all technical assistance
- d. Vaccine introduction working groups: These teams are technical teams that develop detailed workplans for implementation
- e. New Vaccines Steering Committees? Set up to supervise the NVI working groups
- f. Political goodwill?
- g. Public perception of the vaccine.
 - a. Would affect acceptability and demand
 - b. What advocacy and communication needs?

Decision making process – Health Impact



- a. What is the current morbidity and mortality data on RSV (Accuracy, availability, dependability of data have to be taken into account)
Routine data sources is most preferred rather than survey.
- b. Risk of epidemics: What is the impact of an epidemic, What is the risk to population are there other ways to mitigate the epidemic etc.
- c. Other approaches to control/combat RSV: Are they available, cost and feasibility of using the different approaches.
- d. RSV relative to other health problems that resources would be directed to?



Implementation feasibility: Vaccine Characteristics

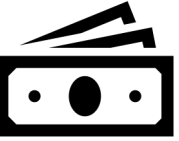
- Vaccine efficacy and impact
- Vaccine formulation, presentation, packaging and labelling
 - How many doses?
- Packed volume per dose
 - Affects storage requirements of the vaccine
- Cold chain requirements
 - Refrigerated or ambient temperatures
- Vaccine availability and supply
- Vaccine safety profile
 - Adverse events following immunization (AEFI)
 - Adverse events of specific interest (AESI)



Implementation feasibility: Programmatic implications

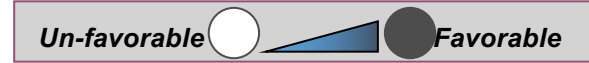
- a. Delivery mode – oral, injectable and required volume
- b. **Delivery strategy – Fixed posts, campaigns, outreaches etc.**
- c. Implication to existing policies, guidelines
- d. Vaccination schedule, extra visits
- e. Training requirements for health workers
- f. Cold chain needs RSV vaccine
- g. Documentation requirements
- h. Booster doses

Feasibility of vaccine introduction: Economic and financing of the vaccine



- a. Is it value for money?
- b. Costs for vaccine
- c. Vaccine delivery/ running costs
- d. Economic evaluation studies
 - Cost effectiveness
 - Cost of vaccine introduction and implementation
 - Budget impact
- e. Sustainability beyond introduction period
 - Long term financing of vaccine cost and running costs

Scorecard used to assess NVI opportunity



Potential for impact	Health impact	Other impact considerations
	<p>Decrease child mortality and morbidity:</p> <ul style="list-style-type: none"> • Xxx 	<p>Epidemics potential:</p> <ul style="list-style-type: none"> • Xxx
Feasibility	<p>Decrease overall mortality and morbidity:</p> <ul style="list-style-type: none"> • xxx 	<p>Equity and other social implications:</p>
	Implementation feasibility	Financial implications
	<p>Adequacy of supply and Vaccine presentation:</p> <ul style="list-style-type: none"> • xxx 	<p>Vaccine procurement costs</p> <ul style="list-style-type: none"> • With GAVI support: xxx • Beyond GAVI support: xxx
	<p>Ease of integration within RI programme</p> <ul style="list-style-type: none"> • Synergies on vaccine schedule: xxx • Cold chain readiness: xxx 	<p>Other operational costs</p> <ul style="list-style-type: none"> • Cold chain logistics: xxx • Training and social mobilization: xxx

1. Assume able to obtain 8% share in market – equivalent to top 3/5 player
 Source: Kalorama, Datamonitor, IMS, literature search, BCG analysis

Proposed next steps on RSV introduction strategy

- ✓ **How do we get a RSV strategy properly documented into Kenya's immunization policy and CMYP**
 - ❑ Develop analysis need based on information gaps
 - ❑ Carry our analysis and/or task key groups to fill the information gaps
 - ❑ Provide information to KENITAG
 - ❑ Develop strategy to be housed in CMYP and next policy update

- ✓ **Developing a structure to review the RSV and overall New Vaccine Introduction strategy regularly**
 - ❑ What issues and data should the KENITAG take into account
 - ❑ What additional NVI options should be considered by the NITAG
 - ❑ How should KENITAG recommendations be taken into account
 - ❑ How often should the review of the strategy be done

Summary

- RSV introduction into Routine Immunization Program would require evidence on burden of disease
- Stakeholders involvement is key in ownership
- The Country's transition from Gavi support is a key consideration on sustainability
- Community Awareness is critical in creating demand for the vaccine.
- Programmatic implications of introduction should be considered.

Thank you